



August 21, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration Room 1061  
5630 Fishers Lane  
Rockville MD 20852

Sent electronically: 8/21/00

RE: Docket #00N-1351

Food Labeling: Use of the term "fresh" for foods processed with alternative, non-thermal technologies

Ladies and Gentlemen:

Thank you for the opportunity to respond to your request for comments on whether or not the term "fresh" would be truthful and not misleading on foods processed with alternative technologies. As an observer at the public meeting held on July 21, 2000 in Chicago, I want to compliment the organizers and facilitators of that meeting in providing straight forward and pertinent information as well as directing public comments so that they were brief, constructive, and to the point.

This letter is being written on behalf of Sun Orchard, Inc., a national manufacturer and distributor of premium citrus juices with manufacturing facilities in Arizona, California and Florida. All of our products today are minimally processed by way of a high temperature, short time (HTST) pasteurization process. However, for 15 of the 16 years that we have been in business, we manufactured and distributed fresh juices. Through this experience, and our unfortunate involvement with a product recall as a result of a food borne illness, we have had very direct dialog with consumers in regard to their understanding and expectations associated with a fresh product.

This letter will outline our beliefs in response to the eleven questions that were outlined in the public notice that appeared in the Federal Register on July 3, 2000. Our response to these questions are as follows:

**1. DO CONSUMERS ASSOCIATE THE TERM "FRESH" WITH ORGANOLEPTIC CHARACTERISTICS, NUTRITIONAL CHARACTERISTICS, OR SOME OTHER CHARACTERISTICS?**

-It is our experience that consumers associate "fresh" with a food or juice product that is in its raw state and has not been subjected to further processing. More specifically, "fresh" as it applies to juice, is therefore a product, in its finished and marketed form, that has not undergone any further processing after its extraction from the fruit to affect the flavor, appearance, nutritive content, and natural bacterial and enzyme content of the juice.

00N-1351

@33

## 2. DO CONSUMERS WANT A WAY TO IDENTIFY FOODS THAT TASTE AND LOOK FRESH, BUT HAVE BEEN PROCESSED TO CONTROL PATHOGENS?

-We believe very definitively that consumers do want to have the knowledge as to whether or not a food or juice has been treated to control pathogens. In addition, they would like to know what that treatment has been to destroy or control pathogens. Consumers today are more aware of food safety and want the necessary information to make the consumption decision. They are more sensitive to this information and the risks they may be exposed to with fresh juice as a result of the sophistication in tracking food-borne illnesses and the intense media attention associated with these risks and illnesses.

## 3. WHAT DOES INDUSTRY THINK THE TERM "FRESH" MEANS?

-Industry views the definition of "fresh" the same as the consumer does (see answer to question one above). To emphasize, it is believed that "fresh" is a juice in its finished form that has not undergone any processing to affect the flavor, appearance, nutritive content and the natural beneficial or detrimental bacteria in the raw product.

## 4. IS THE TERM "FRESH", WHEN APPLIED TO FOODS PROCESSED WITH THE NEW TECHNOLOGIES, MISLEADING TO CONSUMERS?

-Yes, we believe that it is misleading because there will be great confusion in the mind of the consumer if the label "fresh" includes unpasteurized or untreated products, as well as those which have been treated by existing or alternative technology to destroy pathogens. The consumer will have no point of reference for consumption risk and may shy away from the entire juice category.

## 5. DO THE NEW TECHNOLOGIES PRESERVE THE FOODS?

-There's no question that existing and alternative technologies (including thermal and non-thermal processes), extend the shelf life of juice. Fresh juice generally has a stated shelf life of fourteen to seventeen days, and many of the existing alternative technologies (including the HTST thermal process we use), extend the shelf life dramatically. In some instances, this shelf life may be increased by seven to ten days, while other technologies increase shelf life as much as six months. Clearly, existing or new technologies that treat juice will extend shelf life and preserve the juice.

## 6. ARE THE NEW TECHNOLOGIES TRULY NON-THERMAL?

-It is our belief that thermal or non-thermal processing is irrelevant in analyzing the "fresh" definition since key considerations should be whether or not the juice is in its finished, unprocessed state or whether it has been treated to affect the natural bacteria (harmful or non-harmful), or to affect the natural product's enzymatic activity. In addressing the whole issue of fresh, we question why finished unpasteurized juice that

is frozen (a thermal treatment) yet untreated for shelf life purposes or harmful bacteria is not defined as a fresh product. Once thawed, the shelf life and risk from bacteria is the same as the original finished product. We also question why juice that has been made from cold stored fruit is defined as fresh. Fruit which is cold stored for as much as five months has been thermally stored and as a result of the natural decay process is susceptible to contamination since the Brix level is high, the acid level is low (high ph) and the incidence of rotten and spoiled fruit is also high.

**7. ARE THERE QUANTIFIABLE PARAMETERS (eg. LEVELS OF NUTRIENTS, VITAMINS, ETC.) THAT COULD BE MEASURED TO DETERMINE IF A FOOD IS "FRESH"?**

-We have found with our process (HTST pasteurization), that we have been able to provide a finished product that has the same nutritional and qualitative characteristics of fresh juice. Therefore, even though the nutritional and qualitative aspects of fresh juice can be duplicated, we do not believe the product should be labeled as "fresh" since we have extended shelf life, destroyed the target pathogens and further processed the finished product.

**8. IS THERE A TERM OTHER THAN "FRESH" THAT CAN BE USED WITH THE NEW TECHNOLOGIES?**

-We believe it is extremely important that the label have a description as to what process has been utilized to treat the finished juice and to destroy and eliminate pathogens. Whether the alternative technology is HTST pasteurization, high pressure, ultra violet light, irradiation, carbon dioxide with pressurization or any other process, it is imperative that the consumer understand what process has been used and as a result, differs from fresh, unprocessed juice. The consumer then needs to be educated, or aware of, the side effects (positive and negative) of this additional process.

**9. WOULD CONSUMERS UNDERSTAND A NEW TERM?**

-Yes, as long as the descriptor outlined in question eight is provided on the label, we do not believe that confusion or misunderstanding would occur.

**10. WHAT IS THE ECONOMIC IMPACT OF ALLOWING USE OF THE TERM "FRESH" FOR FOODS PROCESSED WITH NEW TECHNOLOGIES?**

-Over the last two years we have explored and been exposed to a number of the alternative technologies that are being tested for eliminating pathogens in unpasteurized juice and extending its shelf life. In many instances, the claims made by the developers of the alternative technology have not been fully proven to be successful in generating the required five-log reduction or to fully eliminate or destroy pathogens. If the process has been proven to be successful, the next step is to determine if this process can be

utilized by a manufacturer who requires high volume with a continuous flow of product. The technologies which have cleared both of the prior hurdles, tend to be extremely expensive and in the case of the smaller fresh and premium juice manufacturers, very difficult to afford the initial investment and find a true cost benefit from this investment. If the term "fresh" is allowed to be used for new technologies, we think it is only fair for the "fresh" label to be allowed for existing technologies that have been perfected and which leave the finished product with the same characteristics of a fresh product, like specialized HTST pasteurization. Manufacturers like Sun Orchard have already invested substantial sums of money in equipment that will eliminate pathogens yet retain the characteristics of a fresh juice. If only the new technologies were defined as "fresh", an unfair benefit would be provided to the large, multi-national juice manufacturers who can afford the large investment in these new technologies. Additionally, we believe that the entire juice marketplace would be negatively impacted and reflected in market share declines as a result of the confusion that would exist in understanding whether or not the product in front of the consumer is fresh and unpasteurized bearing certain risks, or if it has been treated to eliminate harmful bacteria.

Over the last three years, it has been interesting to see that the customer of our product in the foodservice segment of the marketplace, has not been willing to pay a greater price to receive a safer product since they believe it should be provided to them as the customer or consumer assumes automatically. Therefore, a manufacturer like us is forced to absorb the additional burden of the capital investment.

#### 11. WOULD ALLOWING THE TERM "FRESH" ON FOODS PROCESSED WITH NEW TECHNOLOGIES, PLACE SMALL FIRMS NOT ABLE TO USE THESE TECHNOLOGIES, AT AN ECONOMIC DISADVANTAGE?

-Yes, small firms would definitely be at an economic disadvantage due to the financial resources of the larger companies, coupled with the benefits that the extended shelf life would have on the distribution process. All of us in the fresh and premium juice category have built our businesses around our ability to distribute a high quality product, with a short shelf life, very quickly after the juice has been manufactured. The large juice manufacturers have had great difficulty in distributing and properly handling the short shelf life juice without negatively impacting the quality. By allowing them the ability to define their product with a multi-month shelf life as fresh, all fresh and many premium juice companies would be eliminated within a reasonable period of time.

In summary, we at Sun Orchard recommend the following:

A. The definition of "fresh" should not include a juice which has been further processed by a new alternative technology.

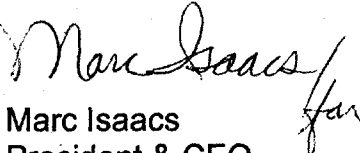
B. Any juice further processed under any subsequent technology should include on the label a description of this alternative technology.

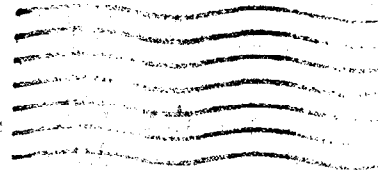
C. If it is found necessary to include new technologies in the definition of "fresh", we believe it is only appropriate to include all processes after juice extraction, including thermal processes, that do not diminish the fresh character (flavor and appearance) of the finished product.

If there are any questions regarding our position, please do not hesitate to contact me.

Sincerely,

SUN ORCHARD, INC.

  
Marc Isaacs  
President & CEO



Dockets Management Branch (HFA-305)  
Food and Drug Administration Room 1061  
5630 Fishers Lane  
Rockville MD 20852

1198 WEST FAIRMONT DRIVE, TEMPE, ARIZONA 85282

